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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/162,984	12/08/1993	HERVE BOUCHARD	12907281	4803
5487	7590	05/11/2005	EXAMINER	
ROSS J. OEHLER AVENTIS PHARMACEUTICALS INC. ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			TRINH, BA K	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/162,984

Applicant(s)

BOUCHARD ET AL.

Examiner

Ba K. Trinh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/18/2005 AND 2/2/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 140-154 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 140-154 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/18/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 140-154 are pending.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 140-154 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,441,026(Bissery). Although the conflicting claims are not identical, they are not patentably distinct from each other because the currently claimed cyclopropyl taxotere has been disclosed in Bissery patent which is useful to treat a variety of cancer diseases, note compound in column 4 of the patent. The composition of Bissery has also been taught in the current disclosure, note compound (I) in page 1 and pages 45-47 of the same. There is not a patentable distinctness between the current compound and the composition of Bissery since the composition is in use for medical practice and it comprises the compound(the major ingredient) and a pharmaceutical carrier(s). When the patent term of the composition is expired, the composition (and the compound as well) will no longer be protected and is in public domain. A patent for the compound can not be enforced afterward since it is in conflict with the public interest. This also applies to the method of use since it is known and disclosed in the Bissery patent.

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Applicant remarks filed on 1/18/2005 and 2/2/2005 and Dr. Bissery's Declaration had been considered, but not found persuasive. The declaration shows that the current cyclopropyl taxotere does not have any unobvious and/or unexpected results over the prior art taxotere when the same is combined with another therapeutic substance to form a composition. The results in the Declaration is unpredictable. In Dr. Bissery's US patent 6,441,026, only synergistic results of the cyclopropyltaxotere composition are present; noted lines 40 to 44 column 6 of the patent.

In pages 46 to 48, Applicant teaches that the current cyclopropyltaxotere can be used alone as well as in combination with a variety of therapeutic substances, the teachings are substantially identical to the patented composition of US 6,441,026. In Paper #7 dated 8/23/94 and Paper # 18 dated 1/23/1995 of the instant application, Examiner had made restriction requirement wherein the compound cyclopropyltaxotere, the composition and method of use are grouped together, and Applicant does not traverse the restriction requirement; noted the remarks in Paper # 13 dated 11/22/1994. In Paper #24 dated 4/20/1995, Applicant canceled the composition claims by choice and in pursuant of the compound claims 140-142 in an interference. During the time that the current application is awaiting the interference outcome, Dr. Bissery filed the composition claims for patent and matured as US Patent 6,441,026 on 08/27/2002. The current claimed invention contains the compound and method claims excluding the composition claims. The prosecution record clearly shows that the claimed invention and the patented invention of Dr. Bissery belong to a single concept of invention.

When the US Patent 6,441,026 expires, cyclopropyltaxotere and the composition containing the same should be in the use of public domain, granting the current composition

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with a full patent term would prolong the protection of Applicant's cyclopropyltaxotere and its uses. The "evergreening" of the current compound should not be permitted.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

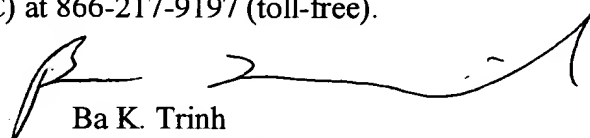
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ba K. Trinh whose telephone number is (571) 272-0695. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ba K. Trinh
Primary Examiner
Art Unit 1625

TRINH/BKT

09 May 2005